UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA *et al.*, *ex rel.* MARY BIXLER WOOD,	:	
Plaintiffs,	:	14 Civ. 4958 (ER)
v.	:	
AVALIGN TECHNOLOGIES, INC., *et al.*,	:	
Defendants.	:	
UNITED STATES OF AMERICA,	:	
Plaintiff-Intervenor,	:	
v.	:	
AVALIGN TECHNOLOGIES, INC. and INSTRUMED INTERNATIONAL, INC.,	:	
Defendants.	:	

STIPULATION AND ORDER OF SETTLEMENT AND PARTIAL DISMISSAL AS TO DEFENDANTS AVALIGN TECHNOLOGIES, INC. AND INSTRUMED INTERNATIONAL, INC.

WHEREAS, this Stipulation and Order of Settlement and Dismissal ("Stipulation") is entered into by and among plaintiff the United States of America (the "United States" or "Government"), by its attorney, Geoffrey S. Berman, United States Attorney for the Southern District of New York; the relator Mary Bixler Wood ("Relator"), by Relator's authorized representatives; and defendants Avalign Technologies, Inc. ("Avalign") and Instrumed

International, Inc. ("Instrumed") (collectively, "Defendants" and, together with the Government and Relator, the "Parties"), by their authorized representatives;

WHEREAS, in or about July 2014, the Relator filed a Complaint under the *qui tam* provisions of the False Claims Act ("FCA"), 31 U.S.C. § 3729 *et seq.*, against Defendants and several other entities ("Relator Complaint"). The Relator Complaint alleges that Defendants violated the FCA (and corresponding state and local laws) by, among other things, selling medical devices to customers who then sold directly or indirectly to hospitals and other health care providers for use in medical procedures for which claims for reimbursement were submitted to federal health care programs, while knowing that the devices were not approved or cleared for marketing by the United States Food and Drug Administration ("FDA") pursuant to the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, and were not exempt from the FDCA's premarket approval or clearance requirements as "pre-amendment devices" (*i.e.*, devices that were, among other things, legally marketed prior to the May 28, 1976, the effective date of the Medical Device Amendments of 1976);

WHEREAS, the Government alleges that at various times between 2007 to 2014 (the "Covered Period"), Instrumed, a subsidiary of Avalign, (1) sold the medical devices listed in Rider 1, which Instrumed claimed qualified as "pre-amendment devices" and, thus, were exempt from the FDCA's premarket approval or clearance requirements, (2) knew that the devices did not in fact qualify as "pre-amendment devices," and (3) caused the devices to be sold to customers, who then sold them to hospitals and other health care providers for use in medical procedures for which claims for reimbursement were submitted to Medicare and Medicaid. The conduct described in this Paragraph is the "Covered Conduct" for purposes of this Stipulation;

WHEREAS, contemporaneous with the filing of this Stipulation, the Government is filing a Notice of Election to Partially Intervene and Complaint-In-Intervention in the above-referenced *qui tam* action ("Government Complaint"), in which it is asserting claims against Defendants under the FCA;

WHEREAS, Defendants intend to enter into separate settlement agreements with certain states impacted by the Covered Conduct (collectively, the "States") to resolve claims asserted by the States for the Covered Conduct (the "State Agreements"), and have agreed to pay a total of $1,371,559.40 to the States pursuant to the State Settlements;

WHEREAS, the Parties have, through this Stipulation, reached a mutually agreeable resolution addressing the claims asserted against Defendants by the Government and in the Relator Complaint, for the Covered Conduct;

NOW, THEREFORE, upon the Parties' agreement IT IS HEREBY ORDERED that:

TERMS AND CONDITIONS

1. The Parties agree that this Court has subject matter jurisdiction over this action and consent to this Court's exercise of personal jurisdiction over each of them.

2. Defendants admit, acknowledge and accept responsibility for the following conduct:

   a. Devices, as defined in 21 U.S.C. § 321(h), are subject to regulation by the FDA. Before certain devices can be marketed, they must be cleared by the FDA, pursuant to Section 510(k) of the FDCA. However, if a device qualifies as a "pre-amendment device," it is exempt from the Section 510(k) requirements.

   b. According to FDA guidance, pre-amendment status may be established through (1) the direct proof method, e.g., submitting documents showing that the device

was placed in interstate commerce and was actually labeled and promoted for a specific intended use prior to May 28, 1976; (2) the sworn statement method, e.g., submitting a sworn statement from a current or former company employee or other credible person that the device was in interstate commerce prior to May 28, 1976; or (3) some combination of those two methods. For a manufacturer such as Instrumed to claim that a particular device qualifies for the pre-amendment status exemption, the manufacturer must be able to demonstrate, among other things, that the device was legally marketed in the United States prior to May 28, 1976, and that the device had not been significantly changed or modified since then, and for which a classification regulation requiring premarket approval has not been issued by FDA.

c. In February 2009, Instrumed's then-head of Quality and Regulatory Affairs acknowledged in an email in response to an inquiry about an Instrumed device, that "we cannot claim pre-amendment because Instrumed was not selling/marketing this device before May 28, 1976."

d. By no later than April 2009, representatives of Instrumed and CareFusion Corporation ("CareFusion"), a customer of Instrumed pre-amendment devices and distributor of those devices, began exchanging correspondence regarding whether Instrumed and CareFusion could legitimately rely on Instrumed's invocation of the pre-amendment status exemption to market its devices. This exchange of correspondence continued for approximately one year.

e. Throughout these exchanges, CareFusion repeatedly informed Instrumed that the evidence Instrumed was relying on to justify its claim that certain devices

qualified for the pre-amendment status exemption—evidence consisting of excerpts from a catalogue issued by the devices' original manufacturer, not Instrumed, and an affidavit from an Instrumed employee—was insufficient.

i. Subsequently, in May 2010, CareFusion informed Instrumed that its affidavit was "too general to be of value."

ii. In October 2010, CareFusion again informed Instrumed that its affidavit was insufficient, including because it lacked "[s]pecific device codes and associated product names" and "[a] statement, with any supporting documentation, of the specific intended uses for which the device was labeled and promoted."

iii. In further correspondence in November 2010, CareFusion reiterated its concerns about the affidavit to Instrumed, and noted that, "[i]n order for an affidavit to be useful, we would need someone to confirm that they are aware that you were making a specific product and the product you are currently selling has not substantially changed since May, 1976."

iv. In that same correspondence, CareFusion described having "several meetings" with Instrumed regarding the affidavit, and that "it was determined that we could not establish pre-amendment based on your documentation."

f. Instrumed never provided CareFusion a satisfactory affidavit to justify its claim that the devices qualified for the pre-amendment status exemption.

g. In 2012, Instrumed's Vice President of Quality and Regulatory Assurance at that time opened a Corrective and Preventative Action ("CAPA") that set forth a plan to compile supporting documentation because Instrumed had "[n]o evidence of selling devices claimed as pre-amendment."

h. The day after the CAPA was opened, the daughter of Instrumed's founder confirmed that she was unable to locate any documentation to show these devices had been marketed prior to May 28, 1976.

i. In March 2014, the FDA issued a warning letter indicating that it had determined that Instrumed's devices "are not pre-amendment devices that were legally on the market in the United States prior to May 28, 1976."

j. Instrumed responded to the warning letter by submitting to the FDA a "Pre-Amendment Device Determination Request" for some of the devices identified by the FDA, including copies of the previous manufacturer's catalogue pages to support pre-amendment status. After FDA provided feedback to Instrumed in May 2014, Instrumed decided to discontinue sale of these products and conducted a recall of these products.

k. In May 2015, FDA rejected Instrumed's determination requests as insufficient.

l. Throughout the Covered Period, Instrumed continued to sell the devices in Rider 1.

m. Some of the devices were then sold by Instrumed's customers to hospitals and other medical providers, and used in procedures for which providers submitted claims for reimbursement to federal health care programs.

3. Defendants shall pay to the Government within fourteen (14) business days of the Effective Date (defined below in Paragraph 28) the sum of $8,128,440.60 plus interest, which shall be compounded annually at a rate of 2.87% accruing from May 30, 2019, through the date of payment (the "Settlement Amount") in accordance with instructions to be provided by the Financial Litigation Unit of the United States Attorney's Office for the Southern District of New York. Of the Settlement Amount, $4,064,220.30 constitutes restitution to the United States.

4. Defendants agree to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Stipulation. Upon reasonable notice, Defendants shall encourage, and agree not to impair, the cooperation of their directors, officers, and employees, and shall use their best efforts to make available, and encourage, the cooperation of former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals. Defendants further agree to furnish to the United States, upon request, complete and unredacted copies of all non-privileged documents, reports, memoranda of interviews, and records in their possession, custody, or control concerning any investigation of the Covered Conduct that they have undertaken, or that has been performed by another on their behalf.

5. Subject to the exceptions in Paragraphs 9 and 14 below (concerning excluded claims and bankruptcy proceedings), and conditioned upon Defendants' full compliance with the terms of this Stipulation, including full payment of the Settlement Amount to the United States pursuant to Paragraph 3 above, the United States releases Defendants, including their subsidiaries and corporate predecessors, successors and assigns, from any civil or administrative monetary claim that the United States has for the Covered Conduct under the FCA, the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a, the Program Fraud Civil Remedies Act, 31 U.S.C. § 3801-

3812, and the common law theories of fraud, payment by mistake, and unjust enrichment. For avoidance of doubt, this Stipulation does not release any current or former officer, director, employee, or agent of Defendants from liability of any kind.

6. Defendants fully and finally release the United States, its agencies, officers, employees, servants, and agents from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that Defendants have asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, employees, servants, or agents related to the Covered Conduct and the United States' investigation, prosecution and settlement thereof.

7. Conditioned on Defendants' timely payment of the full Settlement Amount pursuant to Paragraph 3 above, the Relator, for the Relator and Relator's heirs, successors, attorneys, agents, and assigns, releases Defendants, including their subsidiaries and corporate predecessors, successors and assigns, as well as all of their current and former officers, directors, employees, attorneys, and other agents, from any and all manner of claims, proceedings, liens, and causes of action of any kind or description that the Relator has against Defendants related to or arising from the Covered Conduct; provided, however, that nothing in this Stipulation releases any claims against any other defendant in the Relator Complaint; provided further that nothing in this Stipulation shall preclude Relator from seeking to recover Relator's reasonable expenses and attorneys' fees and costs pursuant to 31 U.S.C. § 3730(d).

8. In consideration of the execution of this Stipulation by the Relator and the Relator's release as set forth in Paragraph 7 above, Defendants, including their subsidiaries, predecessors, and corporate successors and assigns, as well as all of their current and former officers, directors, employees, attorneys, and other agents, release the Relator and Relator's successors, heirs, assigns,

attorneys, and other agents, from any and all manner of claims, proceedings, liens, and causes of action of any kind or description that Defendants have against Relator related to or arising from the Covered Conduct, provided, however, that nothing in this Stipulation shall preclude Defendants from asserting any defenses to any claims the Relator may assert for expenses, costs or attorney's fees pursuant to 31 U.S.C. § 3730(d) in connection with the Covered Conduct. Further, nothing in this Stipulation shall preclude Defendants from asserting any claims or defenses they may have against Relator in connection with claims asserted by Relator that are unrelated to the Covered Conduct.

9. Notwithstanding the releases given in Paragraph 5 above, or any other term of this Stipulation, the following claims of the Government are specifically reserved and are not released by this Stipulation:

a. any liability arising under Title 26, United States Code (Internal Revenue Code);

b. any criminal liability;

c. except as explicitly stated in this Stipulation, any administrative liability, including but not limited to the suspension and debarment rights of any federal agency; mandatory or permissive exclusion from Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) or 42 U.S.C. § 1320a-7(b) (permissive exclusion); suspension or debarment pursuant to 2 C.F.R. Part 376; or actions pursuant to, or otherwise consistent with, 42 C.F.R. § 52.9, 45 C.F.R. §§ 75.207- 75.208, or 45 C.F.R. §§ 75.371-75.375;

d. any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;

e. any liability based upon obligations created by this Stipulation; and

f. any liability of individuals.

10. Defendants shall be in default of this Stipulation if Defendants fail to make the required payment set forth in Paragraph 3 above on or before the due date for such payment, or if they fail to comply materially with any other term of this Stipulation that applies to them. ("Default"). The Government shall provide written notice to Defendants of any Default in the manner set forth in Paragraph 27 below. Defendants shall then have an opportunity to cure the Default within ten (10) calendar days from the date of delivery of the notice of Default. In the event that a Default is not fully cured within ten (10) calendar days of the delivery of the notice of Default ("Uncured Default"), interest shall accrue at the rate of 12% per annum compounded daily on the remaining unpaid principal balance of the Settlement Amount, beginning ten (10) calendar days after mailing of the notice of Default. In the event of an Uncured Default, Defendants shall agree to the entry of a consent judgment in favor of the United States against Defendants in the amount of the Settlement Amount as attached hereto as Exhibit A. The United States may also, at its option, (a) rescind this Stipulation and reinstate the claims asserted against Defendants in the Government Complaint; (b) seek specific performance of this Stipulation; (c) offset the remaining unpaid balance of the Settlement Amount from any amounts due and owing Defendants by any department, agency, or agent of the United States; or (d) exercise any other rights granted by law, or under the terms of this Stipulation, or recognizable at common law or in equity. Defendants shall not contest any offset imposed or any collection undertaken by the Government pursuant to this Paragraph, either administratively or in any Federal or State court. In addition, Defendants

shall pay the Government all reasonable costs of collection and enforcement under this Paragraph, including attorneys' fees and expenses. In the event that the United States opts to rescind this Stipulation pursuant to this Paragraph, Defendants shall not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any civil or administrative claims that relate to the Covered Conduct.

11. The Relator and Relator's heirs, successors, attorneys, agents, and assigns shall not object to this Stipulation; Relator agrees and confirms that the terms of this Stipulation are fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B).

12. Defendants, having truthfully admitted to the conduct set forth in Paragraph 2 hereof (the "Admitted Conduct"), agree that they shall not, through their attorneys, agents, officers, or employees, make any public statement, including but not limited to, any statement in a press release, social media forum, or website, that contradicts or is inconsistent with the Admitted Conduct or suggests that the Admitted Conduct is not wrongful (a "Contradictory Statement"). Any Contradictory Statement by Defendants, their attorneys, agents, officers, or employees, shall constitute a violation of this Consent Order, thereby authorizing the Government to pursue any of the remedies set forth in Paragraph 10 hereof, or seek other appropriate relief from the Court. Before pursuing any remedy, the Government shall notify Defendants that it has determined that Defendants have made a Contradictory Statement. Upon receiving notice from the Government, Defendants may cure the violation by repudiating the Contradictory Statement in a press release or other public statement within four business days. If Defendants learn of a potential Contradictory Statement by their attorneys, agents, officers, or employees, Defendants must notify the Government of the statement within 24 hours. The decision as to whether any statement constitutes a Contradictory Statement or will be imputed to Defendants for the purpose of this

Stipulation, or whether Defendants adequately repudiated a Contradictory Statement to cure a violation of this Stipulation, shall be within the sole discretion of the Government.

13. Defendants waive and shall not assert any defenses Defendants may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Stipulation bars a remedy sought in such criminal prosecution or administrative action.

14. Defendants represent and warrant that they have reviewed their financial situation, that they are currently solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(I), and that they reasonably believe that they shall remain solvent following payment to the Government of the Settlement Amount. Further, the Parties warrant that, in evaluating whether to execute this Stipulation, they (a) have intended that the mutual promises, covenants, and obligations set forth constitute a contemporaneous exchange for new value given to Defendants, within the meaning of 11 U.S.C. § 547(c)(1); and (b) have concluded that these mutual promises, covenants, and obligations do, in fact, constitute such a contemporaneous exchange. Further, the Parties warrant that the mutual promises, covenants, and obligations set forth herein are intended to and do, in fact, represent a reasonably equivalent exchange of value that is not intended to hinder, delay, or defraud any entity to which Defendants were or became indebted to on or after the date of this Stipulation, within the meaning of 11 U.S.C. § 548(a)(l).

15. If within 91 days of the Effective Date of this Stipulation or any payment made under this Stipulation, Defendants commence any case, action, or other proceeding under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors or a third party commences

any case, action, or other proceeding under any law related to bankruptcy, insolvency, reorganization, or relief of debtors (a) seeking an order for relief of Defendants' debts, or seeking to adjudicate Defendants as bankrupt or insolvent; or (b) seeking appointment of a receiver, trustee, custodian, or other similar official for Defendants or for all or part of Defendants' assets, Defendants agree as follows:

a. Defendants' obligations under this Stipulation may not be avoided pursuant to 11 U.S.C. § 547, and Defendants shall not argue or otherwise take the position in any such case, action, or proceeding that (i) Defendants' obligations under this Stipulation may be avoided under 11 U.S.C. § 547; (ii) Defendants were insolvent at the time this Stipulation was entered into; or (iii) the mutual promises, covenants, and obligations set forth in this Stipulation do not constitute a contemporaneous exchange for new value given to Defendants.

b. If any of Defendants' obligations under this Stipulation are avoided for any reason, including, but not limited to, through the exercise of a trustee's avoidance powers under the Bankruptcy Code, the Government, at its option, may rescind the release in this Stipulation and bring any civil and/or administrative claim, action, or proceeding against Defendants for the claims that would otherwise be covered by the release in Paragraph 5 above. Defendants agree that (i) any such claim, action, or proceeding brought by the Government would not be subject to an "automatic stay" pursuant to 11 U.S.C. § 362(a) as a result of the case, action, or proceeding described in the first sentence of this Paragraph, and Defendants shall not argue or otherwise contend that the Government's claim, action, or proceeding is subject to an automatic

stay; (ii) Defendants shall not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any claim, action, or proceeding that is brought by the Government within 60 calendar days of written notification to Defendants that the release has been rescinded pursuant to this Paragraph, except to the extent such defenses were available on July 2, 2014; and (iii) the Government has a valid claim against Defendants in the amount of the Settlement Amount and the Government may pursue its claim in the case, action, or proceeding described in the first sentence of this Paragraph, as well as in any other case, action, or proceeding.

c. Defendants acknowledge that the agreements in this Paragraph are provided in exchange for valuable consideration provided in this Stipulation.

16. Defendants agree to the following:

a. Unallowable Costs Defined: All costs (as defined in the Office of Management and Budget ("OMB") Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards published at 2 C.F.R. §§ 200 *et seq.*; the Department of Health and Human Services adoption of the OMB Guidance provided at 45 C.F.R. § 75, subpart E *et seq.*; the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47 where applicable; or otherwise as specified by federal statutes, regulations or the terms and conditions of a Federal award) incurred by or on behalf of Defendants, including their present or former officers, directors, employees, and agents in connection with:

(1) the matters covered by this Stipulation;

(2) the United States' audit(s) and civil investigation(s) of matters covered by this Stipulation;

(3) Defendants' investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil investigation(s) in connection with matters covered by this Stipulation (including attorneys' fees);

(4) the negotiation and performance of this Stipulation; and

(5) any payment Defendants make to the United States pursuant to this Stipulation and any payment Defendants may make to the Relator, including expenses, costs and attorneys' fees;

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program (FEHBP) (hereinafter referred to as "Unallowable Costs").

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by Defendants, and Defendants shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Within 90 days of the Effective Date of this Stipulation, Defendants shall identify and repay by adjustment to future claims for payment or otherwise any Unallowable Costs (as defined in this Paragraph) included in payments previously sought by Defendants from the United States. Defendants agree that the United States, at a minimum, shall be entitled to recoup from Defendants any overpayment plus applicable

interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted requests for payment. Any payments due shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States, including the Department of Justice and/or the affected agencies, reserves its right to audit, examine, or re-examine Defendants' books and records and to disagree with any calculation submitted by Defendants or any of their subsidiaries or affiliates regarding any Unallowable Costs included in payments previously sought by Defendants, or the effect of any such Unallowable Costs on the amounts of such payments.

d. Nothing in this Stipulation shall constitute a waiver of the rights of the United States to audit, examine, or re-examine Defendants' books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

17. Defendants agree that they waive and shall not seek payment for any of the health care billings covered by this Stipulation from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.

18. This Stipulation is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity except as otherwise provided herein.

19. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Stipulation; provided, however, nothing in this Stipulation shall preclude the Relator from seeking to recover Relator's expenses or attorneys' fees and costs from Defendants, pursuant to 31 U.S.C. § 3730(d).

20. Any failure by the Government to insist upon the full or material performance of any of the provisions of this Stipulation shall not be deemed a waiver of any of the provisions hereof, and the Government, notwithstanding that failure, shall have the right thereafter to insist upon the full or material performance of any and all of the provisions of this Stipulation.

21. This Stipulation is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Stipulation is the United States District Court for the Southern District of New York. For purposes of construing this Stipulation, this Stipulation shall be deemed to have been drafted by all Parties to this Stipulation and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

22. This Stipulation constitutes the complete agreement between the Parties with respect to the subject matter hereof. This Stipulation may not be amended except by written consent of the Parties.

23. The undersigned counsel and other signatories represent and warrant that they are fully authorized to execute this Stipulation on behalf of the persons and the entities indicated below.

24. This Stipulation is binding on Defendants' successor entities.

25. This Stipulation is binding on the Relator's successors, transferees, heirs, and assigns.

26. This Stipulation may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Stipulation. E-mails that attach signatures in PDF form or facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Stipulation.

27. Any notice pursuant to this Stipulation shall be in writing and shall, unless expressly provided otherwise herein, be delivered by hand, express courier, or e-mail transmission followed by postage-prepaid mail, and shall be addressed as follows:

TO THE UNITED STATES:

Monica Folch
Sharanya Mohan
Assistant United States Attorneys
United States Attorney's Office
Southern District of New York
86 Chambers Street, Third Floor
New York, New York 10007
Email: monica.folch@usdoj.gov
sharanya.mohan@usdoj.gov

TO DEFENDANTS:

Anne Walsh
Hyman Phelps & McNamara P.C.
700 13th Street N.W. #1200
Washington, D.C. 20005
Email: awalsh@hpm.com

28. The effective date of this Stipulation is the date upon which the Stipulation is approved by the Court (the "Effective Date").

Agreed to by:

THE UNITED STATES OF AMERICA

Dated: New York, New York
~~July~~ August 2, 2019

GEOFFREY S. BERMAN
United States Attorney for the
Southern District of New York

By: _____
SHARANYA MOHAN
MÓNICA FOLCH
Assistant United States Attorneys
86 Chambers Street
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sharanya.mohan@usdoj.gov
monica.folch@usdoj.gov
Attorneys for the United States of America

RELATOR

Dated August 1, 2019
August 1, 2019

By: _____
MARY BIXLER WOOD

Dated: Rochester, New York
August 1, 2019

HARTER SECREST & EMERY LLP

By: _____
BRIAN MARC FELDMAN
1600 Bausch & Lomb Place
Rochester, New York 14604
Telephone No. (585) 231-1201
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bfeldman@hselaw.com
Attorneys for Relator

DEFENDANTS

Dated: Washington, DC
July 30, 2019

HYMAN, PHELPS & MCNAMARA

By: _____

ANNE WALSH
700 13th Street N.W. #1200
Washington, D.C. 20005
Tel.: (202) 737-4592
Email: awalsh@hpm.com
Attorney for Defendants

SO ORDERED:

_____

HON. EDGARDO RAMOS
UNITED STATES DISTRICT JUDGE

Dated: Aug. 13, 2019

RIDER 1 – DEVICE LIST

Product Code	Item Number
DRC (Trocar)	500-01938
DRC (Trocar)	500-01943
DRC (Trocar)	500-01948
DRC (Trocar)	500-01953
HAX (Tong, skull for traction)	630-05401
HAX (Tong, skull for traction)	638-05401
HAX (Tong, skull for traction)	638-05433
HAX (Tong, skull for traction)	638-05437
HBG (Drills, burrs)	600-00499
HBG (Drills, burrs)	600-00566
HBG (Drills, burrs)	600-00509
HBG (Drills, burrs)	590-06501
HBG (Drills, burrs)	590-05389
HBG (Drills, burrs)	650-11864
HBG (Drills, burrs)	600-00561
HBG (Drills, burrs)	600-00514
HBG (Drills, burrs)	600-00549
HBG (Drills, burrs)	600-00479
HBG (Drills, burrs)	600-01091
HBG (Drills, burrs)	600-00484
HBG (Drills, burrs)	600-00553
HBG (Drills, burrs)	600-00571
HBG (Drills, burrs)	600-00591
HBG (Drills, burrs)	600-00616
HBG (Drills, burrs)	590-06506
HBG (Drills, burrs)	590-06491

HBG (Drills, burrs)	590-06496
HBG (Drills, burrs)	600-00529
HBG (Drills, burrs)	600-00534
HBG (Drills, burrs)	600-00539
HBG (Drills, burrs)	600-00601
HBG (Drills, burrs)	600-00606
HBG (Drills, burrs)	606-00566
HDC (Tenaculum, uterine)	310-21138
HDC (Tenaculum, uterine)	310-21113
HDC (Tenaculum, uterine)	310-21098
HFX (Clamp, circumcision)	330-86212
HFX (Clamp, circumcision)	330-86112
HHK (Curette, suction, endometrial)	320-05942
MGZ (Valvulotome)	500-05669
MGZ (Valvulotome)	500-05664
MGZ (Valvulotome)	500-05626
MGZ (Valvulotome)	500-05631
MGZ (Valvulotome)	500-05636
MGZ (Valvulotome)	500-05656
MGZ (Valvulotome)	500-05660